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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,321	11/22/2000	Richard A. Shimkets	15966-599 (CURA-99)	3118

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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/22/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/718,321

Applicant(s)

SHIMKETS ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 27, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 29-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Search Results 1 and 2.

DETAILED ACTION

1. Applicant's election without traversal of Group III, claims 29-31, SEQ ID NO: 400, in Paper No. 19, filed December 04, 2002, is acknowledged.
2. It is acknowledged that claims 1-28 and 32-44 have been cancelled.
3. Claims 29-31 are examined on the merits.

IDS

4. Document C29 of Paper 14, filed March 04, 2002, has not been considered because International Search Reports are not published documents.
5. The information disclosure statements, Paper Nos. 12 and 15, filed April 29, 2002 and March 02, 2001, respectively, fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It is noted that this instant application file lacks the documents listed on the said information disclosure statements. They have been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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8. Specific to claim 29, lines 2-3, the “phrase polymorphic nucleic acid sequence comprising SEQ ID NO:400” causes the claim to be vague and indefinite. The limitation of polymorphic nucleic acid sequence conflicts with the specific limitation of SEQ ID NO:400. The scope of the limitation, polymorphic nucleic acid sequence, includes sequences that may vary from the claim sequence by sequence length or specific nucleic acid at specific position(s). However, the limitation of SEQ ID NO:400 is specific to the disclosed sequence which may have nucleic acid [G/A] at position 26. It is unclear which limitation is controlling the metes and bounds of the claimed invention. Clarification of the metes and bounds is required. Claims 30 and 31 are rejected due to being dependent from claim 29.

9. Specific to claim 30, lines 1-2, the phrase “polypeptide is translated in the same open reading frame as is a wild type protein” causes the claim to be vague and indefinite. It is unclear how a polypeptide is further translated? Clarification of the metes and bounds is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 29-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

12. The introduction of nucleotide corresponding to position 26 of SEQ ID NO:400 is not a guanosine is considered to be new matter because of no written basis as filed. It is

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acknowledged that applicants disclose the polymorphic site a position 26 is [G/A]. However, the claim sequence where position 26 of SEQ ID NO:400 is not a guanosine is different from the disclosure as originally filed as non-being inclusive of T or C nucleotide residues.

LACK OF UTILITY UNDER 35 U.S.C. § 101:

13. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

14. The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

15. Claims 29-31 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

16. The claimed subject matter is not supported by a specific and substantial utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a “real world” use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

17. The critical limitation of claims 29-31 is the polypeptide encoded by the polynucleotide SEQ ID NO: 400 (page 69, row 3). It is acknowledged that Applicants disclose an isolated polypeptide comprising a polymorphic site wherein the protein is encoded by one of the nucleotide sequences SEQ ID NO:1-1468 (Page 6, lines 24-28). Further, the polypeptide can be related to one of the protein families such as ATPase associated protein, cadherin, or any of the other proteins provided in Table 1, column 10 (Page 7, lines 3-5). The polymorphic nucleotide sequence, which encodes an isolated polypeptide, may be used in treating a subject suffering from, at risk for, or suspected of, suffering from a pathology ascribed to the presence of a sequence polymorphism in a subject (Page 8, lines 5-21). However, the claimed polypeptide and the encoding polymorphic nucleotide sequence is not supported by a specific asserted utility because the disclosed relationship of the claimed polypeptide to other protein families and intended utilities fall short of any readily available utility for the claimed sequence. These are

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non-specific uses that are applicable to nucleic acids and polypeptides in general and not particular or specific to the polynucleotide or polypeptide being claimed.

18. Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, the protein produced as a final product resulting from processes involving the nucleic acid does not have asserted or identified specific and substantial utilities. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved, such as the latent transforming growth factor beta binding protein 1 encoded by SEQ ID NO: 400, does not define a "real world" context for use. Similarly, the other listed utilities and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to many such compounds.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

21. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

22. The claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above (refer to 35 U.S.C. § 101 rejection), one skilled in the art would not know how to use the claimed invention without undue experimentation.

LACK OF WRITTEN DESCRIPTION

23. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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24. The specification discloses SEQ ID NO: 400, which corresponds to DNA encoding a polypeptide. Claim 30 is directed to encompass polypeptides that are translated in the same open reading frame as the wild type whose amino acid sequence is identical to the amino acid sequence (see 35 U.S.C. 112, second paragraph rejection, paragraphs 6 and 7). None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

25. With the exception of SEQ ID NO: 400, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

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...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

26. Therefore, only SEQ ID NO: 400 but not the full breadth of the claim 30 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

27. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

28. Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nakamura (JP 1994092995-A 3).

29. Nakamura discloses a large subunit of TGF-beta-masking protein hMPU-3 encoded by a nucleic acid sequence. The sequence is identical to SEQ ID NO:400 except for position 26 because the said sequence contains a guanosine at position 26 (See Search Result 2). However, the complement of the Nakamura sequence is not a guanosine at position 26, therefore, it fully

anticipates the limitation of the complement of SEQ ID NO:400, wherein the nucleotide corresponding to position 26 is not a guanosine.

30. Claims 29 and 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nakamura (JP 06092995-A).

31. Nakamura discloses a human masking protein subunit hMPU-3 encoded by a nucleic acid sequence which complements SEQ ID NO:400 (See Search Result 1). Further, the human masking protein subunit hMPU-3 of Nakamura contains an adenosine at position 26, therefore, it fully anticipates the limitations wherein the nucleotide of SEQ ID NO:400 corresponding to position 26 is an adenosine but not a guanosine.

CONCLUSION

32. NO CLAIM IS ALLOWED.

33. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

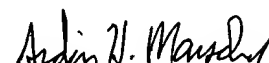
34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

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36. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
4/17/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER